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14. ABSTRACT It is widely acknowledged that cardiovascular disease prevention requires intervention as early in the human lifespan as practical. A window of opportunity presents in early adulthood when students gain independence as young adults attending university. In a three-phase investigation, this study will evaluate the behavioral patterns of university students in the domains of diet, exercise, stress management, smoking and sleep (phase 1). Informed with information from phase 1, a pilot study (phase 2) will test the feasibility of performing an intervention in university students consisting of an 8-week period during which the students will receive three text messages (by phone or iPad) per week, tailored to address the behavioral issues that the student has identified as needing improvement and for which the student has indicated a desire to make change. Using lessons learned in phase 2, a randomized, controlled trial of the 8 week intervention (phase 3) will be performed with the plan to compare the outcomes of behavior change, measures of anthropomorphic data, and serum markers of cardiovascular risk to test the impact of the intervention.				
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ARCPEP 2 Continuation Project (Seton Hill University)

Annual Report

Dates: 9-27-12 to 9-26-13

Executive Summary

The collaborative relationship between Walter Reed and Seton Hill University has been dynamic, to include a site visit to the university and a day long Healthy Engagement Coaching Workshop conducted by ICHP colleagues for Seton Hill University students at Walter Reed. Project staff has been hired to assist with the equipment purchasing, renovations, logo development and patient recruitment plan of action. The vendor has been selected and the contract executed to build the Seton Hill University application to be utilized during phase 2 of the project. Phase 1 of this proposal is an observational study and will begin January 2013.

Introduction

This study aims to study the issues of health behaviors in the domains of nutrition, exercise, stress, sleep and smoking. We aim to improve health behaviors in these domains by evaluating lifestyle choices, learning styles, and communication preferences with a three-phase investigation.

Phase I has the specific objective of lifestyle assessment. Phase 2 constitutes a pilot study in a limited number of university students to determine the feasibility of causing healthy behavior change by health coaching and the use of electronic messaging to university students. Phase 3 will measure improvements in the lifestyle behaviors of students as a result of health coaching and electronic feedback messages.

Body

Walter Reed location:

1. Continued oversight, research and data management coaching via weekly telephonic conference calls and emails.
2. Provided direct "hands-on" teaching with statistical methods using summary statistics, analysis of variance and correlation analysis.
3. Wrote, edited, rewrote and coached on writing abstracts.
4. In collaboration with the Scientific Team, developed a schedule of academic conferences with abstract due dates and meeting dates and locations.
5. Reviewed and updated database from Phase 1 data, performed quality checks on data entries and requested corrections from original completed questionnaires.
6. Advised on focus group formation, IRB approval for focus groups, and content of material to be introduced for focus group feedback.
7. Chaired discussions on a developing list of topics for more intense data analysis in order to facilitate preparation of manuscripts for publication on Phase 1 data.
8. Met in person with Dietetic Staff and Students from Seton Hill to give a lecture entitled, "Introduction to Research Methods"

Seton Hill location:

The following deliverables were completed in the year from 27 September 2012 to 26 September 2013:

- On 25 March 2013 Seton Hill University Institutional Review Board approved annual review application
- On 10 April 2013 SHUPEP team submitted annual review application that had been approved by Seton Hill University Institutional Review Board to HRPO and ORP for secondary approval.
- On 7 May 2013 HRPO and ORP issued secondary approval of SHUPEP protocol.
- On 29 August 2013 SHUIRB approved protocol revision
- On 12 September 2013 three abstracts from preliminary Phase 1 data were submitted to the American College Health Association for consideration for the May 2014 meeting. The abstracts were entitled *Associations Between Anthropometric Measures of College Students and Campus Dining Options*, *Vegetarian-style Eating in College Students: Diet Survey Analysis and BMI*, and *Vitamin D Deficiency in College Students: Prevalence and Implications*.
- On 19 September 2013 another abstract from preliminary Phase 1 data was submitted to the American College Health Association for consideration for the May 2014 meeting. The abstract was entitled *Sleep Quality, not Sleep Quantity, Correlates with Academic Performance*
- On 22 September 2013 the SHUIRB approved protocol amendment concerning focus group procedures

In addition the following tasks were completed at Seton Hill from 27 September 2012 to 26 December 2012:

- Interviewed and hired second health coach
- Oriented newly hired health coach to position and trained on all equipment and study parameters
- Presented poster session on results of pilot testing of Rate Your Plate survey at the Academy of Nutrition and Dietetics Food and Nutrition Conference and Exhibition
- Received and coordinated placement of equipment in labs
- Conducted Open House Information Session on SHUPEP for students and faculty on campus
- Completed CITI training modules
- Drafted HIPAA forms
- Extensively trained senior dietetic students on study equipment
- Submitted protocol with DoD language to SHU IRB committee for review and approval
- Submitted protocol to the SHU Scientific Committee for review and approval
- Researched alarm lab values for inclusion in protocol, reviewing the literature, contacting Excela lab coordinator, and conferring with ICHP colleagues as per recommendation of SHU Scientific Committee
- Collaborated with SHU nurse to establish procedure for abnormal lab values
- Implemented suggested revisions from both committees and submitted for amendment approvals

- Developed recruitment marketing materials and strategies for use pending IRB approval of protocol
- Worked with HJF and WRNMMC colleagues on submission of protocol to IRB
- Organized and composed IRB application to HJF, TATRC, HRPO; among submissions in addition to protocol and informed consent forms were documentation of CITI training modules completed by staff, licensure documentation, Biosketch forms and Conflict of Interest documentation forms
- Researched pedometers
- Researched and ordered curtains, laptop, laptop stand, shredder, blinds, and other miscellaneous equipment for the labs
- Planned for recruitment table in student dining hall pending IRB approval of protocol
- Obtained permission for sending email blast to faculty to obtain permission to visit classes once IRB approval of protocol is obtained
- Communicated with Excelsa Health Lab coordinator to discuss scheduling of phlebotomists for blood draws for phase 1
- Initiated American Council on Exercise Health Coaching curriculum training for Integrative Health Coaches
- Reviewed and responded to Phase I Blue Print received from ICHP colleague

The following tasks were completed at Seton Hill from 27 December 2012 to 26 March 2013

- Installed new electrical service in Bayley 106 to support use of BodPod
- Researched and ordered SHUPEP t-shirts for staff to brand the study
- Researched and ordered pen/post-it combos for recruitment booth
- Worked with application developer over several conference call meetings to tailor study application to our needs
- Participated in a day-long training session with application developers to prepare for study launch
- Trained junior dietetic students with all study equipment and procedures
- Received initial approval of the protocol from the US Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office on February 21, 2013
- Prepared study materials including copies of study documents and participant folders
- Determined appointment logistics and designated staff for all appointments
- Arranged for senior dietetic students to observe/help with study tasks
- Attended numerous study launch preparation meetings
- Provided recruitment presentation for campus Resident Assistants
- Visited over 50 classrooms/teams/other groups to announce study launch and pass out recruitment flyers
- Recorded a podcast to use for recruitment of participants in online classes
- Hosted a booth outside the campus dining hall for one week to recruit for project

- Hosted eight-three hour screening sessions
- Enrolled about 140 participants in the study and had them complete all surveys
- Scheduled enrolled participants for follow-up appointments for body composition and blood draws
- Met with contact at Excelsa Health who will provide blood draw services and mapped out logistics of blood draws
- Submitted annual review application to Seton Hill Institutional Review Board for approval
- In preparation for continuing review approval submission to TATRC and ORP, conducted an extensive literature search to definitively support our research strategies and objectives as sound and safe
- Prepared Performance Appraisal Documents for Clinical Research Coordinator and Health Coach for initial approval by Subaward PI's Senior Supervisor and Human Resource Program Administrator
- Health coaches continued training on the American Council on Exercise Health Coaching curriculum
- Ordered additional study supplies and equipment based on needs assessment

The following tasks were completed at Seton Hill from 27 March 2013 to 25 June 2013:

- Conducted ongoing recruitment of participants for Phase 1 via flyers and word-of-mouth efforts
- Hosted a booth outside the campus dining hall on four days for three hours each day to recruit for project
- Made several recruitment presentations to athletic teams
- Enrolled additional 32 participants into the study in this quarterly report period
- Conducted ongoing processing of clients including completion of informed consent, HIPAA, W-9 form, etc. Completion of surveys in presence of SHUPEP staff so that questions could be answered and completion could be assessed.
- Attended numerous SHUPEP staff meetings to coordinate study efforts and discuss recruitment strategies
- Scheduled and completed appointments for 162 enrolled participants for their body measurements (BODPOD, Bioimpedance, waist/neck circumferences, and blood pressure) and provided Sensewear to assigned participants
- Scheduled and coordinated laboratory blood work appointments with Excelsa Health Phlebotomists for participants' blood draws
- Processed W-9 and W-8BEN tax forms for payment in coordination with the Seton Hill University Business Office once participants completed all aspects of the study
- Organized and maintained participant file folders
- Followed-up with participant no-shows and managed rescheduling of appointments
- Retrieved lab reports from hospital lab for 161 participants

- Identified abnormal values and sent copies to campus nurse per protocol. Scheduled times when participants could pick up their results from SHUPEP study personnel and ask questions. Those with abnormal results were encouraged to discuss further with nurse as per protocol.
- Researched literature concerning vitamin D to better understand lab results
- Encouraged participants to return for second blood draw to compare initial results of vitamin D levels with results from a second lab
- Researched body composition literature in attempt to explain differences in body composition results obtained by different technologies
- Reviewed information about different equations used by the BodPod to determine when each equation should be used
- Completed Performance Appraisals on Clinical Research Coordinator and Health Coaches
- Met with Human Resources Manager concerning SHUPEP summer assistant and liability insurance renewal
- Identified research activities for summer 2013
- Researched additional information on critical values and discussed proposed changes for phase 2
- Researched additional information about blood pressure including information on the athlete heart.
- Reviewed preliminary data, mindful that phase 1 is incomplete
- Verified and standardized technique for taking blood pressure for Phase 2
- Standardized procedures/techniques for body composition measurements for Phase 2
- Researched stress management references and web resources for use on SHUPEP website
- Created draft of Participant Form for Phase 2
- Ordered additional study supplies as needed
- Presented information about SHUPEP to incoming freshmen at two Setonian Days
- Began discussion of theoretical framework on which to base electronic message intervention in Phases 2 and 3
- Met with new IRB co-chair regarding Privacy Officer and Human Subjects Protection Officer positions
- Met with Seton Hill Registered Nurse and Director of Counseling, Disability and Health Services in preparation for Phase 2 intervention
- Both Health Coaches attained Health Coach Certification from the American Council on Exercise

The following tasks were completed at Seton Hill from 26 June 2013 to 25 September 2013.

- Participated in BodPod annual update with company representative
- Met with new IRB co-chairs regarding requirements for SHU Privacy and the Human Subjects Protections Administrator positions

- Researched behavioral health models to determine appropriate theoretical foundation for message development
- Continued weekly article review
- Reviewed preliminary Phase 1 data, completed data analysis, and evaluated findings
- Planned for completion of Phase 1 and initiation of Phase 2
- Continued recruitment of Phase 1 participants via flyers, word-of-mouth, tables/booths
- Held two screening sessions for recruited participants
- Arranged lab blood work appointments
- Performed data collection measurements on 21 participants
- Revised blood pressure directions for Phase 2
- Participated in conference call with Impedimed representative
- Participated in conference calls with ICHP
- Oversaw delivery and set up of waiting room furniture
- Worked with website developer to create SHUPEP website
- Developed iMovie on blood draw procedures for Phase 2 website to inform participants and dietetics students working on SHUPEP
- Determined process to obtain other iMovies on SHUPEP procedures to serve as website content and/or for training purposes for dietetics students
- Coordinated and oversaw photo shoot for website
- Worked on additional Phase 2 website content
- Met with application developer regarding Phase 2 capabilities
- Submitted revised protocol, informed consents, and newly developed health assessment form to SHU IRB
- Developed procedure for focus groups to obtain insight into acceptance of planned messages for Phase 2
- Amended protocol to include focus groups and submitted to SHU IRB
- Worked with Public Relations to obtain additional photos for SHUPEP website
- Completed CITI HIPS CI course
- Provided brief informational presentations to incoming freshmen and their parents about SHUPEP at Setonian Days
- Worked with Business Office on ongoing insurance requirements and materials required for yearly audit
- Submitted four abstracts for consideration for the 2014 American College Health Association meeting
- Researched and ordered office supplies, miscellaneous materials, shirts and software
- Interviewed, hired, and trained five SHUPEP student research assistants
- Supervised dietetic students in SHUPEP activities
- Prepared research presentation for dietetics students

Key Research Accomplishment

Since the time of the last quarterly report, an additional 21 subjects have finished Phase 1 data collection. As of 25 September 2013, a total of 179 subjects have completed Phase 1; one additional subject who has been recruited has not yet completed all data collection.

Reportable Outcomes

The titles of the four abstracts submitted to the American College Health Association for poster session consideration for the May 2014 meeting are shown below. Complete abstracts can be found in the Appendices.

Associations Between Anthropometric Measures of College Students and Campus Dining Options

Sleep Quality, not Sleep Quantity, Correlates with Academic Performance

Vegetarian-style Eating in College Students: Diet Survey Analysis and BMI

Vitamin D Deficiency in College Students: Prevalence and Implications

Conclusions

Phase 1 is approaching completion. Analysis of preliminary data has been prepared for dissemination. Phase 1 will be completed in the next quarter. Data analysis will provide insights to enhance implementation of Phase 2.

References

N/A

Appendices

Abstracts submitted to the American College Health Association for poster session consideration at the May 2014 meeting can be found below.

Poster Title	Associations Between Anthropometric Measures of College Students and Campus Dining Options
Authors	Bowman, T., Sandrick, J., Tracy, D., Roth, A., Harouse-Bell, K., Kashani, M., Vernalis, M., Eliasson, A.
Purpose	The purpose of this poster session is to understand the impact of various campus-dining options on body fat, BMI and weight among college students.
Abstract	University students (n=161; female 72.6%, Caucasian 82%, mean age 19.8yr) were surveyed for meal plans and measured for percent body fat (%BF) and body mass index (BMI). Students with on-campus meal plans had similar %BF (p=0.84) and BMI (p=0.90) compared to students with no meal plans. However, on-campus diners with flex dollars had higher %BF (29% vs 22%, p<0.0005) and BMI (25 vs 24kg/m ² , p=0.04). Flexible spending, not specific dining plans, is associated with increased weight.
Practice Gap	Overweight and obesity are pandemics that include college-aged students.

Students commonly struggle with increased percent body fat and high BMIs despite a personal desire to achieve fitness. Universities are responding to the problem of overweight by offering more diverse dining plan options than ever before. However, the impact of these various campus dining options is not well understood. There is a lack of data about campus dining choices and maintenance of a healthy weight.

- Poster Title** Sleep Quality, not Sleep Quantity, Correlates with Academic Performance
- Authors** Sandrick, J., Eliasson, A., Tracy, D., Harouse-Bell, K., Bowman, T., Roth, A., Kashani, M., & Vernalis, M.
- Purpose** The purpose of this activity is to provide college health professionals with information to allow more useful and accurate guidance to college students who are experiencing daytime fatigue and poor academic performance.
- Abstract** Sleep is essential for learning. However, little evidence validates this theory outside laboratory settings. University students (n=157; female 72%, Caucasian 82%, mean age 20.0±1.9yrs) showed no difference in total sleep time between students with GPA≥ median and those <median (p=0.34). However, high-GPA students reported better sleep quality (p=0.001), shorter sleep latency (p=0.035), less early AM awakening (p=0.029) and less daytime fatigue (p=0.001). Parameters of sleep quality correlate more strongly with academic performance than total sleep time.
- Practice Gap** In their role to promote student health and improve student performance, college health practitioners and student counselors would benefit from the knowledge that sleep quantity (total sleep time) is not the primary goal to improve sleep behaviors among college students. These health professionals should emphasize improving sleep quality with the aim of decreasing time to fall asleep, difficulty staying asleep and resolving the symptom of daytime fatigue.
-
- Poster Title** Vegetarian-style Eating in College Students: Diet Survey Analysis and BMI
- Authors** Harouse-Bell, K., Sandrick, J., Tracy, D., Bowman, T., Roth, A., Kashani, M., Vernalis, M., & Eliasson, A.
- Purpose** The purpose of this poster session is to illuminate the early benefits of vegetarian style eating in a subsample of college students.
- Abstract** In a health assessment, university students (n=161, mean age 19.8yrs) completed Rate-Your-Plate (RYP) questionnaires. Compared to meat-eaters (n=86), vegetarian-style-eaters (n=20) had healthier RYP scores (68.7±5.5 vs 54.6±6.5, p=0.003) and lower BMI (22.2±3.4 vs 24.8±4.1 kg/m², p=0.01). These differences were not due to eating behaviors such as portion control (p=0.46), skipped meals (p=0.19), or stress eating (p=0.39). These results extend prior findings to a younger age than previously described, supporting initiatives for health promotion in college-aged adults.
- Practice Gap** Improved health is one of the many reasons people choose to adopt a vegetarian-style diet. Research has found many health benefits with this type of diet. A vegetarian diet started earlier in life might avert significant risks to health and may be positively associated with the development of certain chronic diseases. Vegetarian style diet choices are usually limited in the collegiate setting, but could be incorporated into more dining options and health education in this population given the benefits documented.
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- Poster Title** Vitamin D Deficiency in College Students: Prevalence and Implications.
- Authors** Roth, A., Sandrick, J., Tracy, D., Bowman, T., Harouse-Bell, K., Kashani, M., Vernalis, M., & Eliasson, A.

Purpose The purpose of this poster session is to illuminate the alarming rates of Vitamin D deficiency in a subsample of college students and discuss the factors associated with deficiency.

Abstract A health assessment of university students (n=161; female 72.6%, Caucasian 82%; mean age 19.8) was conducted in spring. Laboratory including 25-hydroxyvitamin (25-OH) D levels were obtained. Participants completed Rate Your Plate (RYP) survey, which scores dietary quality based on frequency of consumption of 27 food categories. 73.2% of participants had Vitamin D, (25-OH) D deficiency (<20 ng/mL). Participants with normal Vitamin D levels had a more healthful diet by RYP score, compared to those with insufficiency (p<0.05).

Practice Gap Vitamin D deficiency has garnered attention from researchers given the substantial rates of prevalence, especially in geographic regions with less sun exposure and with minority populations. Vitamin D deficiency poses significant risks to health and may be negatively associated with the development of certain chronic diseases. Vitamin D is not commonly tested in the collegiate setting, but could be incorporated into health assessments given the severity of prevalence documented.